K011579

JUN 2 6 2001

Summary of Safety and Effectiveness
Lyphochek® Tumor Marker Control

1.0 Submitter

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Date of Summary Preparation

May 18, 2001

2.0 Device Identification

Product Trade Name:	Lyphochek® Tumor Marker Control
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek® Tumor Marker Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K992172

4.0 Description of Device

Lyphochek® Tumor Marker Control is prepared from human serum with added constituents of human origin and pure chemicals.

The control is provided in lyophilized form for increased stability

5.0 Statement of Intended Use

Lyphochek® Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.

6.0 Comparison of the new device with the Predicate Device

The new Lyphochek® Tumor Marker Control claims substantial equivalence to the Lyphochek® Tumor Marker Control currently in commercial distribution (K992172). The new Lyphochek® Tumor Marker Control has improved open-vial stability claims for CA 27-29, and improved reconstituted freeze-thaw stability claims for PSA, Calcitonin, and ACTH.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Lyphochek® Tumor Marker Control (New Device)	Bio Rad Lyphochek® Tumor Marker Control (Predicate Device)
Similarities		
Intended Use	The Lyphochek® Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	The Lyphochek® Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human serum based	Human serum based
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Differences		
Open Vial Claim	All analytes will be stable for 14 days when stored at 2 – 8°C with the following exceptions: Ferritin and CA 27-29 will be stable for 6 days. ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution.	All analytes will be stable for 14 days when stored at 2 – 8°C with the following exceptions: ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution.
Reconstituted Freeze Vial Claim	All analytes will be stable after reconstituting and freezing for 30 days when stored at –10°C to –20 °C.	All analytes will be stable for 30 days after reconstituting and freezing when stored at –10°C to –20 °C, with the following exceptions: (1) PSA will be stable for 20 days and (2) ACTH and

		Calcitonin do not have frozen stability claims.

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Lyphochek® Tumor Marker Control. Product claims are as follows:

7.1 Once the control is reconstituted, all analytes will be stable for 14 days when stored tightly capped at 2 - 8°C, with the following exceptions: Ferritin and CA 27-29 will be stable for 6 days. ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution. For optimum precision of Ferritin, allow vial to equilibrate for a minimum of 2 hours prior to assay.

7.2 After reconstituting and freezing the control, all analytes will be stable for 30 days when stored tightly capped at -10°C to -20 °C. Once thawed, do not refreeze the control; discard remaining material.

7.3 The control is stable for 3 years and 3 months when stored unopened at 2 - 8°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 6 2001

Ms. Donna Chapman
Quality Assurance/Regulatory Affairs Manager
Bio-Rad Laboraties, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: 510(K) Number: K011579
Trade/Device Name: Lyphochek® Tumor Marker Control
Regulation Number: 862.1660
Regulatory Class: I
Product Code: JJY
Dated: May 18, 2001
Received: May 22, 2001

Dear Ms. Chapman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K011579

Device Name: **Lyphochek® Tumor Marker Control**

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011579

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____